

Appl. No.: 09/870,424

Amdt. dated 04/29/2005

Reply to Office action of January 25, 2005

### REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

Claims 1-45 are pending in the application. The Examiner has designated Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 as drawn to the elected species and Claims 11-12, 14-15, 22-24, 34, 40, and 44-45 as withdrawn. Consistent with 37 C.F.R. §1.141, Applicant respectfully requests recombination of all Claims 1-45 if, as argued below, the generic claims are found to be allowable.

#### Section 103 Obviousness Rejections

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the previously-cited Gentz patent in view of the previously-cited Obi-Tabot patent and newly-cited U.S. Pat. No. 6,491,953 to Sojka *et al.* The Examiner relies upon the Gentz reference as describing formulations for stimulating hair follicle production that comprise collagen, dextran, glutamic acid, cysteine, and EDTA. The Examiner relies upon Obi-Tabot as suggesting the use of denatured collagen and concludes that it would have been obvious to include denatured collagen in the composition of Gentz. The Examiner relies upon the Sojka reference as disclosing a hair growth promoting composition in liquid form that solidifies at below about 33°C. Applicant respectfully traverses this rejection.

As noted previously, the Gentz reference fails to suggest combining gelatin and dextran (i.e., a long-chain carbohydrate) in the same formulation. The Examiner apparently recognizes this and relies upon the Obi-Tabot reference as allegedly providing the motivation to combine gelatin and dextran in the same formulation. However, there is nothing in Obi-Tabot to suggest such a composition.

The Obi-Tabot reference is directed to a method for promoting wound healing by administering an aqueous suspension to the wound, the suspension including collagen type I, ascorbic acid, alpha-tocopherol, and particulate starch hydrolysate. The composition disclosed in Obi-Tabot is applied in the form of a wound dressing. Although the Obi-Tabot patent describes

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several properties of denatured collagen in the column 13 section referenced by the Examiner, there is no suggestion in any section of the cited patent to form Applicant's claimed composition, which is a hydrogel matrix comprising gelatin and a long chain carbohydrate which is solid at temperatures below 33°C. As noted in a previous response, the Obi-Tabot reference actually adds nothing to the Gentz reference, which already discloses the use of gelatin and dextran individually as gel-forming high molecular weight compounds. However, neither the Gentz reference nor the Obi-Tabot reference disclose any compositions that comprise both dextran and gelatin in the form of a hydrogel matrix that is solid at temperatures below about 33°C or the use of such a composition in a method of stimulating hair growth. In fact, the Obi-Tabot reference is not directed to a hair growth stimulating composition at all.

Additionally, the Sojka patent fails to motivate one of ordinary skill in the art to amend the disclosure of Gentz in any manner that is meaningful to the present invention. The Sojka patent is directed to a controlled release composition comprising an adsorbent polymer, an active agent, and a release retardant. The Sojka reference discloses that the composition can be a solid, a semi-solid, or a liquid and does not specify any particular method of administering the composition. It is not clear which portion of the Sojka patent is being relied upon by the Examiner as allegedly teaching a composition administered in liquid form that solidifies at or below about 33°C. Applicants have been unable to determine any section of the reference that suggests such a property. The Sojka patent does teach that the release retardant ingredient of the composition can be liquid or solid at room temperature, but there is nothing in the cited reference to suggest a method of administering a hair growth stimulating composition that comprises administering a composition in liquid form wherein the composition is solid at temperatures below about 33°C, which means the composition must be administered above about 33°C in order for the composition to be liquid at the time of administration. Note that the claims are directed to the properties of the composition as a whole, while the only reference to room temperature in Sojka relates to a single ingredient of the composition (the release retardant), not the composition as a whole. There is simply nothing in any of the cited references to suggest the claimed composition or the claimed use.

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Even if Sojka did expressly teach a composition with such properties, Applicants submit that there would be no motivation to somehow amend the teachings of Gentz to produce a composition that is solid at room temperature, but administered as a liquid. As previously argued, the Gentz reference requires a gel formulation that remains liquid at room temperature and solidifies when applied to the surface of the skin (at about 37°C) (see column 8, lines 53-59). Although the Gentz reference suggests dextran and gelatin as possible gel forming high molecular weight compounds, it only suggests the use of such compounds in gel compositions that exhibit reverse thermal gelation behavior as described above. Thus, the Gentz reference clearly only teaches gel formulations wherein the gel increases in viscosity with increases in temperature (see column 9, lines 52-60). The independent claims of the present application recite that the hydrogel matrix of the invention is administered in liquid form and is solid at temperatures below 33°C. This is directly contrary to the teachings of the Gentz reference, which requires thermoreversible gelation behavior wherein the gelling agents provide a formulation that is liquid at room temperature, but solidifies at physiologic temperature.

Even if Sojka actually taught a composition that is applied as a liquid but solid at room temperature, which Applicant does not believe as explained above, the Examiner has not explained why one of ordinary skill in the art would be motivated to contradict the clear suggestion in Gentz to use reverse thermal gelation gels. As described above, Gentz teaches away from the invention by suggesting gel formulations that thicken as temperature increases, i.e., a reverse thermal behavior gel. The Examiner has not explained why one of ordinary skill in the art would be motivated to ignore this unambiguous teaching in Gentz. In light of the foregoing, Applicant respectfully submits reconsideration and withdrawal of this rejection.

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the above-described Gentz, Obi-Tabot and Sojka references, further in view of the previously-cited Naughton patent. The Examiner relies upon the Gentz, Obi-Tabot and Sojka references as discussed above and relies upon the Naughton reference as teaching the advantageous injection of a hair growth composition. Applicant respectfully traverses this rejection.

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As noted above, the combination of Gentz, Obi-Tabot and Sojka fail to teach or suggest the subject matter of claim 1. Thus, this rejection is untenable under the same analysis set forth above and, for this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection.

In addition, Applicant must again object to the combination of the Naughton reference with the remaining references of record. There is clearly no justification or motivation for combining the references in the manner contemplated by the Examiner. The Examiner continues to allege that the Naughton reference teaches stimulating hair growth using a hydrogel matrix comprising collagen and dextran and concludes that it teaches injection of "similar formulations" as compared to Gentz. However, the sections of Gentz relied upon by the Examiner are directed to gel formulations, which Gentz teaches are to be administered topically, not by injection (col. 8, lines 59-65). Applicants respectfully disagree that one of ordinary skill in the art would be motivated to inject the gel composition of Gentz due to the teachings of Naughton. The Naughton reference only suggests injection of an aqueous suspension. The Examiner is relying on sections of Gentz directed to gel formulations, not aqueous suspensions. Naughton is silent as to injection of a gel formulation of the type described in Gentz. The Naughton reference is directed to a method of forming a cell culture medium that has been conditioned by cells cultured therein. As taught in the reference, the conditioned cell culture medium contains extracellular proteins and cellular metabolites that are believed to imbue the media with pharmaceutical utility (see column 6, lines 27-32 and column 28, line 15 - column 32, line 8). Thus, it is the conditioned cell culture medium that the Naughton reference suggests has pharmaceutical utility, such as the ability to stimulate hair growth. The conditioned cell culture medium of Naughton is not "similar" to the Gentz gel formulations as alleged by the Examiner, and Applicants fail to see how one would be motivated by Naughton to inject the very different gel formulations of Gentz.

In arguing that Naughton teaches "similar" compositions, the Examiner appears to rely in part on an alleged teaching in Naughton of a composition comprising EDTA. However, Naughton does not actually teach any composition containing EDTA. The only mention of EDTA in Naughton is in a list of abbreviations in column 7, which must have been blindly copied from an unrelated patent application because Applicant can find no mention of EDTA at

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any other point in the document. Thus, contrary to assertions made by the Examiner, the injected composition taught in Naughton is not described as including collagen, gelatin, or EDTA, and cannot be viewed as similar to the Gentz formulations. For this additional reason, Applicant respectfully requests reconsideration and withdrawal of any rejection relying on Naughton.

It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

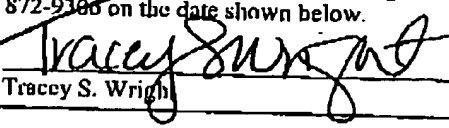
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Tracey S. Wright4/29/05  
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